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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,587	04/19/2000	Vilmos Keri	0100-004	5173

23622 7590 08/28/2002

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**Application No.  
**09/578,587**Applicant(s)  
**Keri et al.**Examiner  
**Irene Marx**Art Unit  
**1651**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 17, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_

4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attachment

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: \_\_\_\_\_

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

10. ☐ Other: \_\_\_\_\_

**IRENE MARX  
PRIMARY EXAMINER  
ART UNIT 1651**

The declaration executed on April 22, 1996 and filed on June 17, 2002 is acknowledged. Claims 4, 6, and 11-16 are being considered on the merits.

The amendment filed June 17, 2002 under 37 CFR 1.116 in reply to the final rejection will be entered upon the filing of an appeal, but is not deemed to place the application in condition for allowance.

***Response to Arguments***

Applicant's arguments and the Polya declaration have been fully considered but they are not deemed to be persuasive.

Applicant argues that the pH used in the Jekkel reference is 10-10.2 and not between 7.5 and 10 as indicated by the examiner. However, claim 11 is directed to a pH of **about 7.5 to about 10** to dissolve the mevinolin in step (a). The declaration is directed to a pH of 9, while claim 12 is directed to a pH between **about 8 and 9**.

With respect to the rejection of claim 11 under 102(e) over Jekkel, the steps of the process "consisting essentially of" steps (a)-(c) are not seen to exclude the use of ion exchange chromatography, since step (b) specifically is directed to "separating the fungal culture medium from the said *Aspergillus* strain to obtain a separated fermentation liquor". See Jekkel, Example 2.

In addition, Applicant's attempt to distinguish the use of ion exchange chromatography in Jekkel's Example 2 over the use of precipitation by acidification in the present invention is noted. However, there is no explicit step in the instant claims requiring "precipitation by acidification" to the exclusion of other steps. The phrase in claim 12 "the improvement which consists essentially of" is not seen as precluding the use of further steps, such as ion exchange chromatography, particularly since the claim preamble includes "separating the strain from the culture medium to obtain a separated culture medium". Further, there is no claim limitation requiring a particular sequence of steps.

With respect to applicant's emphasis that a pH of 7.5-10 is required for the re-dissolution of mevinolin from the fungal cells, it is noted the applicant acknowledged on this record that Jekkel uses a pH of 10-10.2 (Response, page 2, paragraph 7)..

With respect to the Polya declaration, the claims under examination are not directed to a process using the sole strain used in the as-filed specification, i.e., strain *A. obscurus* MV-1 to produce purified mevinolin. In addition, the Polya declaration is directed specifically to this strain and provides no information as to the effect(s) of using any strain within the species *A. obscurus* or *A. terreus*. The claims are directed to unidentified strains of *A. obscurus* or *A. terreus*, the mevinolin-producing properties of which are uncertain; makes the use of a solvent optional, and omits process steps critical to obtaining the crystallized product, such as "filtering, redissolving and recrystallizing", touted in the declaratory evidence.

From the declaration it appears that the favorable results touted in the declaration regarding the absence of contaminants are the result of the combination of the specific mevinolin producing strain cultured, i.e., *A. obscurus* MV-1, and process parameters such as the specific use of pH 9 and pH 2 as well as the use of isobutyl acetate as the solvent. This is not the claim designated invention.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejections are deemed proper and are adhered to.

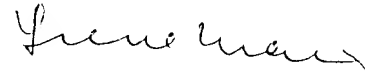
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx  
Primary Examiner  
Art Unit 1651